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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/081,953	02/22/2002	William J. Hennen	4428.2US	6427
24247	7590	03/10/2005	EXAMINER	
TRASK BRITT P.O. BOX 2550 SALT LAKE CITY, UT 84110			CHEN, STACY BROWN	
			ART UNIT	PAPER NUMBER
			1648	

DATE MAILED: 03/10/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/081,953	HENNEN ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Stacy B Chen	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 01 February 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-16 and 18-22 is/are rejected.
- 7) ☒ Claim(s) 17 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 February 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |                                                                                                                        |                                                                                         |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                                                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____                                                |

H/C

### **DETAILED ACTION**

1. Applicant's after-final amendment filed February 1, 2005, is acknowledged and entered.

Claims 1-22 remain pending and examined. Upon further consideration, prosecution in this application is reopened and the finality of the final office action is withdrawn. Any inconvenience is regretted.

2. The objection to claims 1-19 and 22 are withdrawn in view of Applicant's amendment.

The rejection of claims 1-19 and 22 under 35 U.S.C. 112, first paragraph, for containing new matter, is withdrawn in view of Applicant's persuasive arguments. The specification clearly contemplates embodiments of the claimed method wherein the composition comprising transfer factor contained a greater concentration of transfer factor compared to the whole egg. The rejection of claims 11 and 12 under 35 U.S.C. 112, second paragraph, is withdrawn in view of Applicant's amendment. The rejection of claims 20 and 21 under 35 U.S.C. 102(b) as anticipated by Lee (US 5,367,054) is withdrawn in view of Applicant's persuasive arguments.

### ***Claim Rejections - 35 USC § 102***

3. Upon further consideration of the claims and the arguments and prior art of record, the following rejection is reinstated. The Office sincerely regrets any inconvenience to Applicant.

Claims 1-3, 7-16, 18-22 are rejected under 35 U.S.C. 102(b) as being anticipated by Tokoro (5,080,895). The claims are drawn to a method for eliciting a T-cell mediated immune response in an animal, comprising administering transfer factor. The transfer factor is generated by a non-mammalian source animal's egg in response to a T-cell mediated immune response to

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an antigenic agent. The transfer factor molecules have molecular weights of about 4000-5000 Daltons.

Tokoro teaches a method of eliciting an immune response by administering a transfer factor-like component. The transfer factor-like component is produced from eggs of a hen that has been immunized against an antigen. The transfer factor-like component is recovered from a fraction of at most 10,000 in molecular weight (abstract).

In the Declaration of William J. Hennen, Ph.D., submitted December 5, 2001 in parent application USSN 09/667,147 (now patent 6,468,543), Dr. Hennen elaborates on the meaning of the “transfer factor-like component” disclosed in Tokoro (paragraph 13 of the declaration).

(Note that no declaration has been filed in this application, so the contents of the Hennen declaration are discussed here only in order to address some of Applicant’s previous arguments in parent applications. Declarations submitted in parent applications must be resubmitted in child applications for consideration.) One of the references cited by Tokoro provides the background of the term “transfer factor-like component”. The Dunnick reference referred to by Tokoro concludes that “no direct relationship has been established between TFLA (transfer factor-like activity) and in vivo transfers of cellular immunity”. Further, Dr. Hennen says that the antigen used by Tokoro to immunize the hens would not have resulted in a T-cell mediated immune response, merely a B-cell response to ETEC (paragraph 21 of the declaration).

Therefore, given the teachings of Tokoro and the Hennen declaration of record in the parent application USSN 09/667,147, the instant method of eliciting a T-cell mediated immune response to transfer factor is disclosed. However, it is an inherent property of Tokoro’s method, that the animal would elicit a T-cell mediated immune response. Transfer factor would have

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been present in Tokoro's eggs because the hens would have naturally been exposed to antigens that would elicit a T-cell mediated immune response, such as Newcastle disease virus. Whether or not Tokoro actually knew that transfer factor was present, one of ordinary skill in the art would have known that transfer factor would indeed be present because of natural exposure to the antigens that elicit a T-cell mediated response. *Applicant has not shown evidence that Tokoro's hens were never exposed to any pathogen that elicited a T-cell immune response.* Therefore, in the absence of facts supporting the assertion that Tokoro's hens were not exposed to pathogens eliciting T-cell response, the method as claimed is anticipated by the prior art of record.

***Claim Rejections - 35 USC § 103***

4. Claims 4-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tokoro (5,080,895) as applied to claims 1-3, 7-16 and 18-22 above, and further in view of Kirkpatrick *et al* (5,840,700). The claims are drawn to a method of eliciting a T-cell mediated immune response in an animal by administering an extract of an egg including transfer factor formulated for application to the skin of an animal, nasal administration and parenteral administration. The rejection above establishes the Office's position that transfer factor was inherently present in Tokoro's product. Tokoro is silent on these routes of administration, however, one would have been motivated to use them with the product of Tokoro because Kirkpatrick teaches that transfer factor can be administered intravenously, intramuscularly, subcutaneously or orally. Although Tokoro does not explicitly say that transfer factor is present in their product, one would have been motivated to formulate their product for different applications because Tokoro suggests that

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any appropriate route for administration be used (col. 5, lines 29-34). One would have been motivated to administer the transfer factor via other routes depending on the subject receiving it. One would have had a reasonable expectation of success that the product of Tokoro would have been able to formulate it because Kirkpatrick formulates transfer factor in various mediums. Therefore, the invention would have been obvious to one of ordinary skill in the art at the time the invention was made.

### *Conclusion*

5. Claim 17 remains free of the prior art, but objected to for depending from a rejected claim.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stacy B. Chen whose telephone number is 571-272-0896. The examiner can normally be reached on M-F (7:00-4:30). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James C. Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

  
JAMES HOUSEL  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600  
3/7/05



Stacy B. Chen  
March 2, 2005